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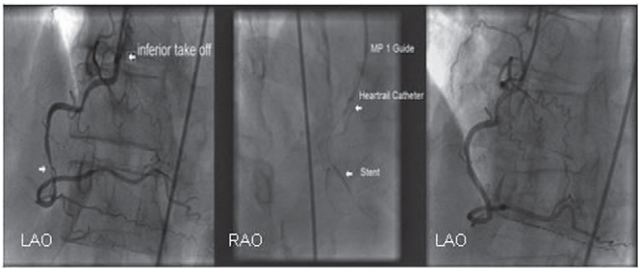

Conclusion: The Heartrail catheter is a safe and effective method in aiding stent delivery in tortuous and calcific vessels involving both the right and left coronary arteries.

TCT-257

Long-Term Follow-up of the Platinum Chromium TAXUS Element (ION) Stent: PERSEUS Two-Year Results

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Background: The TAXUS Element (ION) platinum chromium paclitaxel-eluting stent (PES) incorporates a novel thin-strut design to increase radiopacity and deliverability compared to prior TAXUS stents. Although the ION stent was non-inferior to the TAXUS Express PES in workhorse lesions and superior to the bare metal Express stent in small vessel lesions at 1 year in the PERSEUS studies, longer term outcomes have not been reported.
Methods: PERSEUS Workhorse (WH) is a prospective, Bayesian, 3:1 randomized (ION versus TAXUS Express; Boston Scientific) trial in subjects with lesion length ≤28mm and vessel diameter ≥2.75 to ≤4.0mm which demonstrated non-inferiority for the 12-month primary TLF endpoint. PERSEUS Small Vessel (SV) is a prospective, single-arm trial in subjects with lesion length ≤20mm and vessel diameter ≥2.25 to <2.75mm comparing ION to a matched historical BMS Express control (TAXUS V) which demonstrated superiority for the 9-month primary endpoint (angiographic in-stent late loss).
Results: Clinical events to 2 years are shown (Table). No differences in safety/efficacy measures were observed between stents in PERSEUS WH. Late revascularization rates were reduced by ION in PERSEUS SV.

2-Year Clinical Outcomes	PERSEUS Workhorse			PERSEUS Small Vessel (Propensity-Adjusted*)		
	TAXUS Express (N=316)	ION (N=933)	*P* value	Historical Control BMS (N=125)	ION (N=223)	*P* value
TLF	8.0% (25)	7.2% (66)	0.62	22.7%	9.7%	0.02
MACE	10.6% (33)	10.4% (95)	0.87	31.5%	15.9%	0.02
Cardiac Death	1.0% (3)	1.0% (9)	0.98	1.4%	4.5%	0.15
MI	2.9% (9)	2.7% (25)	0.87	3.1%	1.0%	0.27
Q-wave MI	0.0% (0)	0.8% (7)	0.12	0.4%	0.3%	0.90
Non–Q-wave MI	2.9% (9)	2.0% (18)	0.33	2.7%	0.7%	0.26
TVR	8.4% (26)	8.3% (75)	0.91	28.6%	13.7%	0.02
TLR	5.8% (18)	5.1% (47)	0.64	20.8%	7.1%	0.009
Non-TLR	3.2% (10)	4.0% (36)	0.57	10.1%	8.8%	0.79
All-Cause Death	2.0% (6)	1.4% (13)	0.53	4.1%	5.1%	0.72
Stent Thrombosis (ARC Def/Prob)	0.3% (1)	0.7% (6)	0.50	0.6%	0.3%	0.69

* Logistic regression model (*EuroIntervention* 2011;6:920-927).
Abbreviations: ARC: Academic Research Consortium; BMS: bare metal stent; MACE: major adverse cardiac event (cardiac death, MI, TVR); MI: myocardial infarction; TLF: target lesion failure (including any ischemia-driven revascularization of the target lesion [TLR], myocardial infarction [MI; Q-wave and non–Q-wave] related to the target vessel, or cardiac death related to the target vessel); TVR: target vessel revascularization.

Conclusion: These results suggest that the ION stent provides comparable efficacy to the TAXUS Express stent in workhorse lesions and superior efficacy to the Express stent in small caliber vessels. Safety measures of cardiac death, MI or stent thrombosis are low at 2-year follow-up, demonstrating durable outcomes and successful transfer of the PES technology to the novel platinum chromium thin-strut platform.

TCT-258

Applying the National Institute for Clinical Excellence criteria to patients treated with the Genous EPC capturing stent: A sub-study of the e-HEALING worldwide registry

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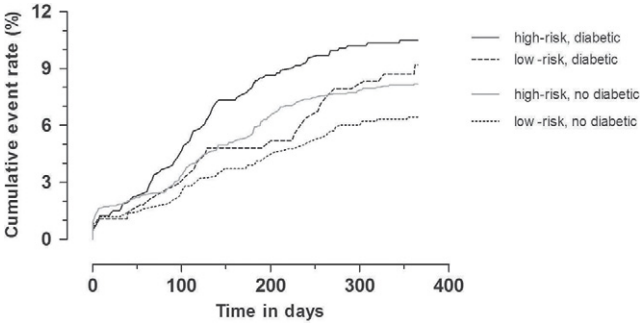
Background: The National Institute for Clinical Excellence (NICE) guidelines recommend the use of bare-metal stents (BMS) in lesions with a low risk of restenosis (diameter≥3mm, length≤15mm) and the use of drug-eluting stents (DES) in lesions with a high risk of restenosis (diameter<3.0mm, length>15mm). While the guidelines were created for DES and BMS, we performed an analysis of patients treated with endothelial cell capturing stents (ECS). ECS are coated with CD34+ antibodies attracting circulating endothelial progenitor cells, thereby accelerating the endothelialization of the stented area.
Methods: We analyzed all 4241 patients enrolled in the worldwide e-HEALING registry that met the NICE criteria for either low-risk or high-risk lesions and were treated with ≥1 ECS. The main study outcome was target vessel failure (TVF) at 12-months, defined as the composite of cardiac death or MI and target vessel revascularization (TVR).
Results: A total of 4241 patients were assessed and at 12-months, TVF occurred in 7.0% of the low-risk patients and in 8.8% of the high-risk patients (p=0.045). When evaluating the diabetic patients versus the non-diabetic patients per risk group, no significant differences were found in TVF, MI or TVR.



Conclusion: ECS show good clinical outcomes in both high- and low-risk lesions according to the NICE guidelines with comparable rates of cardiac death, MI, and stent thrombosis. The TVF rate with ECS was slightly higher in high-risk patients, driven by higher clinically driven TLR. The risk of restenosis with ECS in high-risk patients needs to be carefully considered relative to other risks associated with DES. Furthermore, diabetes mellitus did not influence the incidence of TVF in both risk groups.

TCT-259

Response of Endothelial Progenitor Cells To Antiproliferative Drugs Currently Used in Drug Eluting Stents

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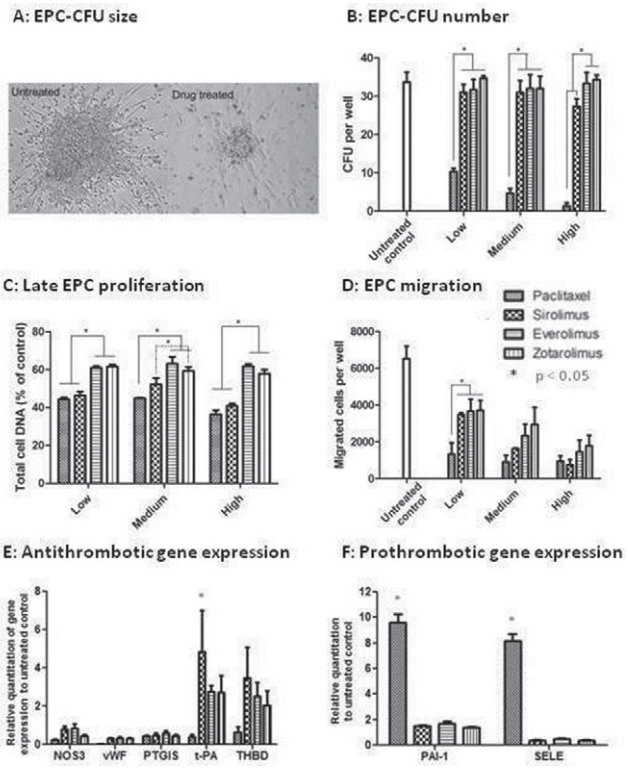
Background: Late stent thrombosis (ST), in drug-eluting stent (DES) recipients, often occurs in the setting of stent struts covered by cells derived from CD34+ endothelial progenitor cells (EPC). We asked the question whether EPC proliferation and function are altered by antiproliferative drugs (APD) present on current DES.
Methods: We studied in vitro the effects of four APD: paclitaxel, sirolimus, everolimus, and zotarolimus on EPC, isolated from peripheral blood of healthy volunteers. Formation of EPC colony forming units (CFU), cell proliferation, antithrombotic and prothrombotic gene expression, release of nitric oxide (NO) and prostacyclin (PGI2), adhesion under flow conditions and cell migration were examined.
Results: Our study indicates that first generation APD (paclitaxel and sirolimus) reduce early EPC CFU formation compared to second generation (everolimus and zotarolimus, A, B). All APD, especially the first generation, also inhibit late EPC proliferation (C). EPC migration (D), release of NO and PGI2, and adhesion are all inhibited by APD, again most notably by paclitaxel and sirolimus. Paclitaxel causes the greatest down-regulation of antithrombotic gene (E) and up-regulation of prothrombotic genes (F).



Conclusion: These results indicate that APD, currently used in DES, particularly paciltaxel, impair EPC proliferation, function and render them prothrombotic. This observation may provide a putative mechanism for late ST seen in DES recipients.

TCT-260

Drug Eluting Stent Failure – Report from the Swedish Angiography and Angioplasty Registry (SCAAR)

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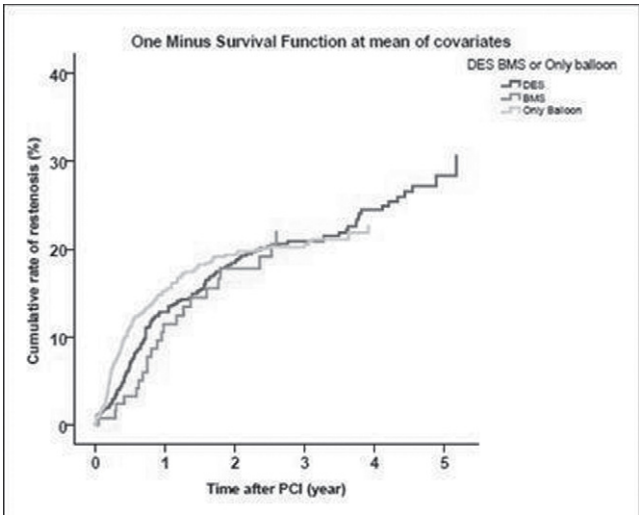
Background: Coronary drug-eluting stent in - stent restenosis (DES ISR) is a growing clinical problem that continues to be one of the most important limitations of PCI. We used the Swedish angiography and angioplasty registry (SCAAR) to investigate occurrence and results of treatment of DES ISR.
Methods: We evaluated results of treatment of in - stent restenosis in a very large patient cohort of all consecutive coronary stent implantations in Sweden between January 1, 2005 and October 06, 2010. The data were analyzed with regard to different types of treatment, patient and stenosis characteristics. 142678 stents (bare metal and drug eluted stens) were implanted and 2126 cases of PCI - treated DES – in- stent restenosis were analyzed.
Results: 1. Neither repeated DES therapy, BMS implantation or plain balloon dilatation is superior in the presence of a DES ISR. 2. Switching between different DES drug coatings in the treatment of DES ISR with repeated DES implantation is not advantageous.



Conclusion: There is so far no therapy of choice in the treatment of DES ISR.

TCT-261

Long-Term Clinical Outcomes From the Zotarolimus-Eluting Stent Program: Final 5-Year Pooled Results From the ENDEAVOR Program

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Background: Emphasis on DES-related outcomes has shifted temporally from early to late occurring events with long-term follow-up identifying trends in safety and efficacy that may distinguish DES.
Methods: Patient level data were combined from 6 prospective randomized and single-arm multicenter trials involving 2,132 patients treated with Endeavor zotarolimus-eluting stents (E-ZES) and 596 patients treated with a bare metal stent (BMS) control. All patients were prospectively followed for 5 years. The recommended minimum duration of dual antiplatelet therapy in all trials was 3 to 6 months regardless of stent type. An independent events committee adjudicated all events. The 2 treatment groups were compared after adjustment for between trial variation and for individual patient clinical and angiographic characteristics by propensity score modeling.
Results: For the first 1,268 E-ZES patients with 5-year follow-up, the cumulative incidence of adverse events for E-ZES and BMS were: death: 5.9% vs 7.6% (adjusted HR: 0.81, p=0.34), cardiac death: 2.4% vs 3.7% (0.83, p=0.57), MI: 3.4% vs 4.8% (0.77, p=0.37), TLR: 7.0% vs 16.5% (0.42, p=0.001), ST (definite or probable): 0.8% vs 1.7% (0.50, p=0.21). Outcomes were consistent across trials and within subgroups at highest risk for adverse events. Very late TLR (Δ=1.6%) and ST (Δ=0.18%) for E-ZES remained stable between 1 and 5 years. Final 5-year safety and efficacy results for the entire program (N=2,132) will be presented.
Conclusion: Through 5 years available follow-up, percutaneous revascularization with ZES compared with BMS was associated with no increased risk of death, myocardial infarction or stent thrombosis, and a significant and durable reduction in repeat revascularization. Final outcomes from completion of the Endeavor ZES program will provide insight to the late-term effectiveness of E-ZES.

TCT-262

Serial Angiographic Follow-Up after Successful Implantation of Sirolimus, Paclitaxel, Everolimus and Zotarolimus-Eluting Stent for Chronic Total Occlusions: Multicenter Registry in Asia

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Background: To evaluate the long-term efficacy of Sirolimus (SES), Paclitaxel (PES), Everolimus (EES) and Zotarolimus-eluting stent (ZES-R/ Endeavor Resolute) on the outcome of patients with chronic total occlusions (CTO).
Methods: A total of 378 patients with 414 CTO lesions (male 72.8%, mean age 69.9 yrs, LAD 49.5%, LCX 21.0%, RCA 26.6%, Others 2.9%) were treated with SES (102 patients 118 lesions, lesion length 36.1±12.9mm, stent length 41.7±15.6mm), PES (108